

Application No. 10/736,489
Response to Office Action dated April 19, 2006
Paper dated June 19, 2006
Attorney Docket No. 4133-031323 (P-6125)

Response Under 37 C.F.R. 1.116
Expedited Procedure
Examining Group 1700

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended): A method for inhibiting adverse reaction of the contents of a ~~prefilled~~ container ~~during~~ subjected to a radiation sterilization procedure comprising:

providing the container made of a composition comprising a polyolefin material and a radiation stabilizer; and

prefilling the container with a medium prior to subjecting the container to a gamma irradiation sterilization treatment, wherein said medium includes less than about 3.4 ppm of oxidizable substances after radiation sterilization.

2. (Original): A method as in claim 1, wherein the medium is selected from the group consisting of a therapeutic fluid and a non-therapeutic fluid.

3. (Original): A method as in claim 2, wherein the medium comprises a drug for parenteral administration to the body.

4. (Original): A method as in claim 2, wherein the medium comprises saline water.

5. (Original): A method as in claim 1, wherein the medium has a pH between about 4.5 and about 7.0 after radiation sterilization.

6. (Original): A method as in claim 1, wherein the medium exhibits ultraviolet absorbance of less than about 0.2 at a wavelength between 220 and 340 nm.

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7. (Cancelled)

8. (Original): A method as in claim 1, wherein the container is manufactured from a composition comprising a polyolefin, a mobilizing amount of a liquid mobilizer compatible with said polyolefin, and a radiation stabilizing amount of a hindered piperidine stabilizer.

9. (Original): A method as in claim 8, wherein the composition of the container further comprises a clarifying amount of a dibenzylidene sorbitol alkyl thioether clarifier.

10. (Original): A method as in claim 8, wherein the composition of the container further comprises a nucleating agent comprising a 2,2'-methylene-bis(4,6-di-t-butylphenol)phosphate salt.

11. (Original): A method as in claim 10, wherein the 2,2'-methylene-bis(4,6-di-t-butylphenol)phosphate salt is selected from the group consisting of sodium 2,2'-methylene-bis(4,6-di-t-butylphenol)phosphate and aluminum 2,2'-methylene-bis(4,6-di-t-butylphenol)phosphate.

12. (Original): A method as in claim 8, wherein the composition of the container further comprises about 0.1 to 10% of an additional polymer.

13. (Original): A method as in claim 8, wherein the polyolefin is selected from the group consisting of polyethylene, polypropylene, polymethylpentene, polytetrafluoroethylene and copolymers thereof.

14. (Original): A method as in claim 8, wherein the mobilizing additive is selected from the group consisting of a hydrocarbon oil, phthalic ester oil, polymer grease, vegetable oil, mineral oil and silicone oil.

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15. (Original): A method as in claim 8, wherein the stabilizer is a bis(4-piperidiny1) diester of a dicarboxylic acid.

16. (Original): A method as in claim 1, where the gamma irradiation ranges from about 10 kGy to about 60 kGy.

17. (Currently Amended): A method of sterilizing a prefilled container comprising:

providing a container made of a composition comprising a polyolefin material and a radiation stabilizer;

filling the container with a medium; and

irradiating said container filled with said medium with gamma radiation, wherein said medium includes less than about 3.4 ppm of oxidizable substances after said irradiating step.

18. (Original): A method as in claim 17, further comprising a step of sealing the container after filling the container with the medium and prior to irradiating the container.

19. (Original): A method as in claim 18, further comprising a step of enclosing the container within packaging after sealing the container, and wherein the irradiating step comprises irradiating said container within said packaging.

20. (Original): A method as in claim 19, wherein said packaging comprises a blister package.

21. (Original): A method as in claim 17, wherein the medium is selected from the group consisting of a therapeutic fluid and a non-therapeutic fluid.

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22. (Original): A method as in claim 17, wherein the medium comprises a drug for parenteral administration to the body.

23. (Original): A method as in claim 17, wherein the medium comprises a saline water.

24. (Original): A method as in claim 17, wherein the gamma radiation is in a range from about 10 kGy to about 60 kGy.

25. (Original): A method as in claim 17, wherein the container is manufactured from a composition comprising a polyolefin, a mobilizing amount of a liquid mobilizer compatible with said polyolefin, and a radiation stabilizing amount of a hindered piperidine stabilizer.

26. (Original): A method as in claim 25, wherein the container further comprises a clarifying amount of a dibenzylidene sorbitol alkyl thioether clarifier.

27. (Original): A method as in claim 25, wherein the container further comprises a nucleating agent comprising a 2,2'-methylene-bis(4,6-di-t-butylphenol)phosphate salt.

28. (Original): A method as in claim 25, wherein the composition of the container further comprises about 0.1 to 10% of an additional polymer.

29. (Original): A method as in claim 25, wherein the polyolefin is selected from the group consisting of polyethylene, polypropylene, polymethylpentene, polytetrafluoroethylene and copolymers thereof.

30. (Original): A method as in claim 25, wherein the container comprises a bag for intravenous fluid delivery.

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31. (Original): A method as in claim 25, wherein the container comprises a syringe.

32. (Currently Amended): A sterilized article comprising:

a container made of a composition comprising a polyolefin material and a radiation stabilizer; and

a medium contained within said container, said medium including less than about 3.4 ppm of oxidizable substances,

wherein said container containing said medium therein has been subjected to a gamma irradiation sterilization treatment after being filled with said medium.

33. (Original): A sterilized article as in claim 32, wherein the medium is selected from the group consisting of a therapeutic fluid and a non-therapeutic fluid.

34. (Original): A sterilized article as in claim 32, wherein the medium contained within the container comprises a drug for parenteral administration to the body.

35. (Original): A sterilized article as in claim 32, wherein the medium comprises saline water.

36. (Original): A sterilized article as in claim 32, wherein the container comprises a bag for intravenous fluid delivery.

37. (Original): A sterilized article as in claim 32, wherein the container comprises a syringe.

38. (Original): A sterilized article as in claim 32, wherein the container is manufactured from a composition comprising a polyolefin, a mobilizing amount of a liquid

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mobilizer compatible with said polyolefin, and a radiation stabilizing amount of a hindered piperidine stabilizer.

39. (Original): A sterilized article as in claim 38, wherein the container further comprises a clarifying amount of a dibenzylidene sorbitol alkyl thioether clarifier.

40. (Original): A sterilized article as in claim 38, wherein the container further comprises a nucleating agent comprising a 2,2'-methylene-bis(4,6-di-t-butylphenol)phosphate salt.

41. (Original): A sterilized article as in claim 40, wherein the 2,2'-methylene-bis(4,6-di-t-butylphenol)phosphate salt is selected from the group consisting of sodium 2,2'-methylene-bis(4,6-di-t-butylphenol)phosphate and aluminum 2,2'-methylene-bis(4,6-di-t-butylphenol)phosphate.

42. (Original): A sterilized article as in claim 38, wherein the composition of the container further comprises about 0.1 to 10% of an additional polymer.

43. (Original): A sterilized article as in claim 38, wherein the polyolefin is selected from the group consisting of polyethylene, polypropylene, polymethylpentene, polytetrafluoroethylene and copolymers thereof.

44. (Original): A sterilized article as in claim 38, wherein the mobilizing additive is selected from the group consisting of a hydrocarbon oil, phthalic ester oil, polymer grease, vegetable oil, mineral oil and silicone oil.

45. (Original): A sterilized article as in claim 38, wherein the stabilizer is a bis(4-piperidiny) diester of a dicarboxylic acid.

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46. (Previously Presented): A method as in claim 1, wherein the radiation stabilizer comprises a liquid mobilizer compatible with said polyolefin.

47. (Previously Presented): A method as in claim 1, wherein the radiation stabilizer comprises a hindered amine stabilizer.

48. (Previously Presented): A method as in claim 17, wherein the radiation stabilizer comprises a liquid mobilizer compatible with said polyolefin.

49. (Previously Presented): A method as in claim 17, wherein the radiation stabilizer comprises a hindered amine stabilizer.

50. (Previously Presented): A sterilized article as in claim 32, wherein the radiation stabilizer comprises a liquid mobilizer compatible with said polyolefin.

51. (Previously Presented): A sterilized article as in claim 32, wherein the radiation stabilizer comprises a hindered amine stabilizer.

52. (Currently Amended): A method as in claim 71, wherein the oxidizable substance is hydrogen peroxide.

53. (Cancelled)

54. (Currently Amended): A method as in claim 5317, wherein the oxidizable substance is hydrogen peroxide.

55. (Previously Presented): A sterilized article comprising:
a container;

and

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a medium contained within said container,
wherein said container containing said medium therein has been subjected to a gamma irradiation sterilization treatment after being filled with said medium, and wherein the medium includes less than about 3.4 ppm of oxidizable substances after said irradiating step.

56. (New) A method as in claim 32, wherein the oxidizable substance is hydrogen peroxide.

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